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Designated 2nd Class OTC drug

Please read the package insert carefully before use and keep it with this medicine.

Antidiarrheal medicine

トメダインフィルム
TOMEDAIN KOWA FILM

Precautions for use

To be avoided

(Failure to follow the directions below may worsen existing symptoms or increase the risk of adverse reactions/accidents)

1. Do not use if you:

- (1) Have had an allergic reaction to this medicine or any of its ingredients.
- (2) Are children under 15 years of age.

2. Do not use the following medicines while taking this medicine.

Gastrointestinal analgesics and antispasmodics

3. Do not drive or operate machinery after use.

(Sleepiness, etc. may occur.)

4. Do not drink alcohol before and after use.

What to ask a doctor, pharmacist or registered salesperson

1. Ask a doctor, pharmacist or registered salesperson before use if you:

- (1) Are currently treated by a doctor.
- (2) Have diarrhea with fever, bloody stool, or continuous mucous stool.
- (3) Have acute severe diarrhea or diarrhea with any of symptoms such as abdominal pain/abdominal bloating/nausea, etc.
(If diarrhea is stopped forcefully with this medicine, the disease may worsen.)
- (4) Have an anal disease, etc. which constipation should be avoided.
(After taking this medicine, constipation may occur.)
- (5) Are pregnant or may possibly be pregnant.
- (6) Are breastfeeding.
- (7) Are elderly.
- (8) Have ever had allergic reaction to any medicines, etc.
- (9) Have the following symptoms:
Dry mouth (a state of being dry in the mouth enough that this medicine does not stay on the tongue)

2. The following symptoms, occurred due to this medicine, may be observed as adverse reactions. If any of the symptoms occur after use, stop use immediately and ask a doctor, pharmacist or registered salesperson with the package insert.

Related area	Symptom
Skin	Rash/redness, itching
Digestive organs	Loss of appetite, abdominal pain, nausea, feeling of fullness in the abdomen, constipation, abdominal distress, vomiting
Psychoneurotic system	Dizziness

The following serious symptoms may rarely occur. In such cases, ask a doctor and receive medical treatment immediately

Name of symptom	Symptom
Shock (anaphylaxis)	Symptoms such as itchy skin, hives, hoarseness, sneezing, itchy throat, difficulty in breathing, palpitation and clouding of consciousness may occur immediately after use.
Oculo-muco-cutaneous syndrome (Stevens-Johnson syndrome), toxic epidermal necrolysis	Symptoms such as high fever, ocular hyperemia, eye discharge, lip erosion, sore throat, widespread rash/redness of the skin, etc. may persist or worsen suddenly.

(Continued overleaf)

Ileus-like symptoms (intestinal obstruction-like symptoms)

Severe abdominal pain, stop of discharge of intestinal gas (flatus), vomiting, or severe constipation with feeling of fullness in the abdomen may occur.

3. The following symptoms may occur after use; in case these symptoms persist or worsen, stop use and ask a doctor, pharmacist or registered salesperson with the package insert.

Sleepiness

4. If symptoms do not improve after using for 2 to 3 days, stop use and ask a doctor, pharmacist or registered salesperson with the package insert.

Indications

Diarrhea due to excessive eating/drinking, diarrhea triggered by cold air while sleeping

Dosage/directions

Take the dose shown below by dissolving in the mouth. However, take at intervals of more than 4 hours. Do not take after diarrhea stops.

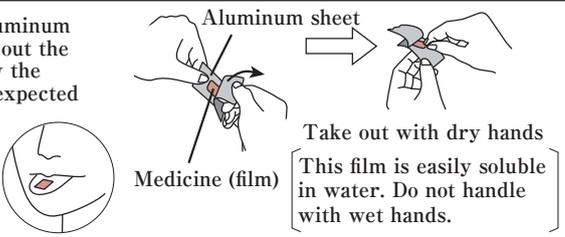
Age	One dose	Daily dose
Adults (15 years and older)	1 film	Twice
Children (Under 15 years of age)	✗ Do not use.	

<Precautions for dosage/directions>

- (1) Follow the dosage/directions.
- (2) Take this medicine (film) as follows.

[1] As shown in the picture, peel the aluminum sheet off from the opening, and take out the medicine (film) only. (Do not swallow the aluminum sheet. It may cause an unexpected accident such as esophageal mucosa penetration, etc.)

[2] Place the medicine (film) on the tongue, which will dissolve with saliva.



- (3) This medicine (film) quickly dissolves in the mouth, but in case it sticks to the throat, flush it down with water. If it feels difficult taking the medicine due to lack of saliva, hold water in the mouth to dissolve and take the medicine.

Ingredients/contents (in 2 films)

Ingredients/contents	
Loperamide hydrochloride	1.0mg

[Inactive ingredients] Hypromellose, hydroxypropyl cellulose, reduced maltose syrup, macrogol, titanium oxide, sodium saccharin, *l*-menthol, Yellow No.5, fragrance, ethanol

Precautions for storage and handling

- (1) Store in a cool and dry place avoiding high temperatures, humidity, and direct sunlight.
- (2) Keep out of reach of children.
- (3) Do not transfer the product to another container. (It may cause misuse and deterioration in the quality.)
- (4) Store and handle this product carefully so as not to break the aluminum sheet or film inside.
- (5) Take the medicine immediately after opening the aluminum sheet.
- (6) Do not use this product after its validity date (printed on the outer box and on the aluminum sheet) has expired.

Marketing Authorization Holder Kowa Company, Ltd. 3-4-14, Nihonbashi-Honcho, Chuo-ku, Tokyo